UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Judge Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06-11337-PBS	)	Magistrate Judge Marianne Bowler

MEMORANDUM BY THE UNITED STATES IN OPPOSITION TO ABBOTT'S MOTION TO COMPEL RESPONSES TO DOCUMENT REQUEST NOS. 37 AND 38

Abbott Laboratories Inc. (Abbott) has moved to compel the United States to produce documents from two categories of material from the Centers for Medicare and Medicaid Services (CMS) or its predecessor, HCFA, as to which the Government has objected based on privilege, lack of relevance, and burdensomeness. The sources for this material are 1) records referred to as "Rulemaking Support Files" and 2) certain documents from CMS's Office of Legislation. The documents withheld reflect the agency's internal deliberations regarding policies under consideration for promulgation in federal regulations and statutes.

Contrary to the assertions in Abbott's brief, the Government has not refrained from producing material reflecting what CMS has known about the actual acquisition costs of drugs over the last twenty or more years. Nor has the Government resisted discovery with respect to drug payment policies actually implemented by the Government. In fact, the United States has produced abundant information on these subjects. As explained below, the Government's objections to the discovery requests at issue pertain to privileged material located in particular

CMS files. Furthermore, the Requests for Production (RFPs) are overbroad and seek material not relevant to the claims or defenses in this case.

I. BACKGROUND

A. The Legal and Factual Backdrop to the Current Discovery Dispute

The United States has brought this action principally under the Federal False Claims Act, 31 U.S.C. § 3729 ("FCA") for damages to the Medicare and Medicaid programs. In order to prevail on its FCA claims, the United States must show that Abbott (1) reported false prices and (2) did so "knowingly," as that term is defined in the FCA. The Government's complaint also states claims for common-law fraud and unjust enrichment. Both Medicare and most Medicaid programs used published Average Wholesale Prices (AWPs) as the pricing points upon which the payment amounts for individual claims were based. The United States alleges that Abbott knowingly created false AWPs that served as the basis for the Government's payments to Abbott's customers (and Abbott itself, under certain circumstances).

In a summary judgment order issued in the MDL on November 2, 2006, Judge Saris determined that the term "AWP" would be construed pursuant to its plain language, and held that AWP "means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies." *In Re Average Wholesale Price Litig.,* 460 F. Supp. 2d 277, 278 (D. Mass. 2006). The United States' First Amended Complaint (FAC) pertains to, essentially, five products[1] for which Abbott created "mega-spreads." "Mega spread" is a term used by Judge Saris to describe situations where the spread created by drug manufacturers for their products was

[1]The five pharmaceutical products are: dextrose solutions, sodium chloride solutions, sterile water, vancomycin, and acyclovir sodium.

between 150 and 900 percent (the "spread" being the difference between the actual price at which a drug could be purchased and the amount paid on a claim for the same drug by government programs and private insurers). *See In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d 20, 40-41 (D. Mass. 2007). The bulk of the drugs in the Government's suit against Abbott exceed even the upper range of the "mega-spread" category described by Judge Saris, carrying spreads from approximately 275 up to 1784 percent, with the majority of the sued-upon spreads exceeding 700 percent. *See* United States' FAC, Ex. 1 (Dkt. 4281).

In light of Judge Saris's summary judgment ruling, there is no real dispute as to whether Abbott reported false prices to the compendia which published Abbott's AWPs for the mega-spread drugs in the FAC given that Abbott has never claimed, either in this action or at any point in the larger MDL, that its published AWPs for the drugs here were equal to or anywhere near the average prices at which those drugs were purchased by Abbott's customers. Furthermore, Judge Saris has found that creation of a "mega-spread," in and of itself, "constitutes egregious misconduct" without even considering whether a defendant marketed such a spread to customers. *See In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d at 95. Accordingly, the principal issue that remains to be litigated in this case concerns Abbott's knowledge – that is, whether Abbott had actual knowledge, acted recklessly, or was deliberately ignorant with respect to the falsity of the prices it reported to the compendia.

B. Abbott's RFPs and the Discovery Already Produced by the U.S.

At this juncture, Abbott has served 142 RFPs on the United States. Whole categories of Abbott's RFPs concern the Government's awareness of actual drug prices and how the emerging evidence of AWP inflation impacted federal payment policies. Abbott's motion to compel pertains to particular sub-categories of material responsive to just two RFPs – numbers 37 and

38. Abbott's RFP 37, in pertinent part, requests documents from 1965 through 2001 "concerning the promulgation of any contemplated, proposed, or actual federal legislation, regulation, or policy concerning payment for drugs under Medicare or Medicaid, including any comments, suggestions, [or] criticisms . . . related to such legislation, regulation, or policy, including but not limited to those listed on [an] attached Schedule B." Abbott's RFP 38 requests documents "relating to actions taken or considered by [the Government] to change the methodology to pay for drugs under Medicare Part B or Medicaid after becoming aware that AWP exceeded the average acquisition costs of Providers for drugs, including the Subject Drugs" [i.e. those in the FAC].

The Government objected to both of the RFPs as overly broad, vague, unduly burdensome, seeking documents which are publicly available (and thus accessible to Abbott) and seeking material that is neither relevant to any claims or legitimate defenses, nor reasonably calculated to lead to the discovery of admissible evidence. The Government also objected that the requests seek documents protected by the deliberative process and attorney-client privileges.

1. The Government's Document Production

At the heart of Abbott's motion to compel is the assertion that the documents it seeks "are relevant because they illuminate what the Government knew about prescription drug pricing and the spreads between AWP and actual acquisition costs, as well as reasons for CMS's failure to change its payment methodology in spite of such knowledge." Memorandum in Support of Abbott's Motion to Compel Discovery Responses to its Document Request Nos. 37 and 38 ("Abbott Mem.") at 4. Notwithstanding its relevancy objections and the Court's previous resolution of key legal issues in this case, the United States has produced abundant material

concerning the Government's knowledge of the actual purchase price for drugs and its efforts to understand the drug market.[2]

With respect to "what the Government knew about prescription drug pricing," the United States has produced vast amounts of material on this subject from, among other sources, the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS), as well as tens of thousands of pages of documents from the files of both CMS and the Medicare carriers that administer the Medicare drug benefit. For example, OIG's Office of Evaluation and Inspections (OEI) is the component at HHS which "is responsible for conducting inspections of HHS programs, operations and processes to identify vulnerabilities, to prevent and detect fraud, waste and abuse, and to promote economy, efficiency and effectiveness in HHS programs and operations." *See* 62 Fed. Reg. 55,812 (Oct. 28, 1997). More particularly, it is OEI's job to "conduct data and trend analyses of major HHS initiatives to determine the effects of current policies and practices on program efficiency and effectiveness." *Id.* At this point, the Government has produced tens of thousands of pages from OEI, ranging from the final reports issued by that office which relate to drug prices to the non-public workpapers which include all the information assembled by OEI during an inspection.

Additionally, defendants have had access to the public comment files that are part of CMS's official rulemaking records. With respect to "the reasons" behind regulatory actions take by CMS, those reasons are laid out in the publicly available official record which includes the agency's responses to points and information contained in the public comments. *See, e.g.,* 56 Fed.

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[2] At this point, the Government has produced well in excess of 200,000 pages of material. This page count is in addition to tens of thousands of electronic data files and spreadsheets.

Reg. 59,502**,** 59,521-25 (discussing public comments relating to payment formula for drugs furnished incident to physician's service).

The Government is also continuing to produce or make available for inspection, a significant volume of material covered by Abbott's RFP Nos. 37 and 38. With respect to the items on Abbott's Schedule B (listing the regulations covered by RFP No. 37), CMS maintains official records relating to the regulations it proposes and promulgates. *See* Ex. 1, Declaration of Lisa Parker, ¶ 3. Under CMS's records disposition authority, the "Official Rulemaking Record" consists of the published proposed rule, public comments received in response to the proposed rule, the public comment log prepared by the record keeping office, and any studies. *See id.*, ¶ 5. In addition to the foregoing types of material, CMS also maintains a category of material designated the "Rulemaking Support File" – a class of documents which the Government has declined to produce as discussed herein.

CMS has retained control of the Official Rulemaking Records for six of the nine regulations listed on Abbott's Schedule B. *Id.,* ¶ 8. Custody of the official records for the other three regulations has been transferred to the National Archives. With respect to the six regulations for which CMS retains custody, there are a total of 163 boxes of material. Records indicate that 132 boxes contain public comments, 18 boxes contain "Rulemaking Support File" documents or documents of a similar nature, and 13 boxes contain "unknown documents." *Id.,* ¶ 9. Abbott's motion relates only to the Rulemaking Support Files.[3]

[3] The Government will obtain and review the 13 boxes described only as "unknown" and either produce responsive non-privileged documents or advise Abbott as to the nature of their contents.

Of the 132 boxes from the Official Rulemaking Record which contain public comments, 62 of those boxes have been made available for review by defense counsel to date. The Government previously agreed to recall and make available public comment files for the other Schedule B regulations on a rolling basis.[4] The Government also will arrange for access to the public comment files which have been transferred to the National Archives – notwithstanding that so doing will be burdensome and pointless. However, the Government anticipates that it will object to the production of privileged information in files from the National Archives in the same manner it has for Rulemaking Support File-type documents which are still in CMS's custody.

With respect to material relating to federal legislation, the Government has been producing responses to congressional correspondence prepared by CMS's Office of Legislation, as well as other material from the Office's correspondence files.

2. Depositions of Officials from CMS and OIG

In addition to receiving hundreds of thousands of pages of documents, Abbott has taken extensive oral discovery regarding the information which CMS acquired about actual sales prices for drugs. Abbott has deposed witnesses from every level in the CMS and HHS hierarchy, including former CMS administrators, about notices of proposed rulemaking, public responses thereto, and the articulation of final agency policies issued in the Federal Register. *See, e.g.,* Ex. 2, Testimony of K. Buto, (former HCFA Associate Administrator for Policy) at 253-73 (testifying about regulation relating to 1992 physician fee schedules and CMS's official responses to public comment thereon); Ex. 3, Testimony of N. DeParle, (former HCFA Administrator) at 242-57 (testifying about regulation relating to 1999 physician fee schedules and CMS's official responses

[4] This manner of production is necessary due to the limited space at CMS headquarters and the agency's need to retain physical custody of the Official Rulemaking Record.

to public comment thereon). As for the OIG inspections and audits, the Government has produced OEI personnel for deposition, who, at this point, have testified in depositions which, in duration, collectively span *weeks*.

C. The United States' Objections and the Material Withheld from Production

With respect to RFPs 37 and 38, the Government has declined to produce pre-decisional, deliberative material comprising "Rulemaking Support Files" for the regulations on Abbott's Schedule B and certain non-public files maintained by CMS's Office of Legislation.

Under CMS's current records disposition authority, a "Rulemaking Support File" consists of internal, pre-decisional documents and drafts, including drafts of the rules, internal comments received on the drafts, regulation logs, regulation specifications, preliminary actuarial estimates, internal recommendations and briefing papers. Prior to 2005, internal, pre-decisional documents and drafts that are now maintained in the Rulemaking Support File were considered part of the Official Rulemaking Record. CMS received approval from the National Archives & Records Administration in 2005 to change its policy so that it could segregate and maintain the Rulemaking Support Files apart from the Official Rulemaking Record. As noted above, CMS estimates that 18 boxes containing over 1600 documents comprise the Rulemaking Support File (or Rulemaking Support File-type documents from pre-2005 rulemakings) for six of the regulations on Abbott's Schedule B. The boxes contain internal, pre-decisional documents and drafts reflecting the views and opinions of CMS personnel, the exchange of which is an integral part of the rulemaking process at CMS. *See* Ex. 1, Declaration of Lisa Parker, ¶ 13.

Abbott also has moved to compel material from CMS's Office of Legislation. This office is responsible for responding to issues brought to the attention of CMS by any Member of Congress. Additionally, the Office of Legislation 1) provides leadership on Medicare, Medicaid

and State Children's Health Insurance Program (SCHIP) legislative strategies and 2) advances the policy development process through the analysis and review of health care initiatives and issues. *See* Ex. 4, Declaration of Donald Johnson, ¶ 3. The staff at the Office of Legislation reviews and analyzes CMS legislative and budget initiatives and makes recommendations to higher level officials concerning the costs and impact of these proposals. They also prepare reports and recommendations for the staff in CMS's Center for Medicare Management as well as the CMS Administrator and other Departmental officials about potential modifications to existing and proposed policies that will improve the operation of CMS programs.

The files that have been withheld from production contain documents with hand-written notes, e-mails, and draft CMS memoranda, as well as drafts of legislation, regulations, and OIG and GAO Reports with hand-written marginalia by Office of Legislation staff. In short, the documents reflect the thoughts, opinions and recommendations of an office concerned, virtually exclusively, with the development and refinement of policy. CMS estimates that there are in excess of 14,000 individual documents in the eight boxes of material from the Office of Legislation. *See id*., ¶ 6. Given the volume of material, CMS has not prepared a document-level privilege log.

II. ARGUMENT

A. The Scope of Permissible Discovery Under Fed. R. Civ. P. 26

Rule 34 of the Federal Rules of Civil Procedure provides that "[a]ny party may serve on any other party a request (1) to produce . . . documents . . . which constitute or contain matters within the scope of Rule 26(b) and which are in the possession, custody or control of the party upon whom the request is served." Rule 26(b) thus governs the basic scope of discovery in civil

actions. Section (b)(1) provides that, "[p]arties may obtain discovery regarding any matter, *not privileged*, that is relevant to the claim or defense of any party . . . ." Fed. R. Civ. P. 26(b)(1) (emphasis added). Section (b)(2) of Rule 26 places general limitations on the authority conferred by Section (b)(1). In relevant part, Section (b)(2) provides that: "The frequency or extent of use of the discovery methods otherwise permitted under these rules and by local rule shall be limited by the court if . . . the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues. . . ." Fed. R. Civ. P. 26(b)(2). The limitation in Section (b)(2) "was added by the 2000 amendments to the rules to 'emphasize the need for active judicial use of subdivision (b)(2) to control excessive discovery.'" *Gill v. Gulfstream Park Racing Ass'n Inc.*, 399 F.3d 391, 400 n. 5 (1st Cir. 2005). Significantly, "[d]iscovery of both privileged and unprivileged information may be limited by Rule 26(b)(2)." *Id.* at 400.

In a similar vein, Rule 26(c) authorizes a court, upon a showing of good cause, to make "any order which justice requires" to protect the target of a discovery request from "annoyance, embarrassment, oppression, or undue burden or expense." *Id.* at 402. The Rule specifically contemplates an order "that certain matters not be inquired into, or that the scope of the disclosure or discovery be limited to certain matters." The First Circuit has explained that "the 'good cause' standard in the Rule is a flexible one that requires an individualized balancing of the many interests that may be present in a particular case." *Id.* The privileged nature of a category of requested information constitutes good cause for an order limiting discovery. *Town of Norfolk v. United States Corps of Army Eng's,* 968 F. 2d 1438, 1442, 1463 (1st Cir. 1992) (affirming

issuance of protective order for privileged material); *see also, Ken's Foods, Inc. v. Ken's Steak House, Inc*., 213 F.R.D. 89, 94-98 (D. Mass. 2002) (denying motion to compel on grounds that common interest privilege protected responsive documents).

Finally, each of these principles - relevance and privilege - operates separately. Irrelevant material is insulated from discovery under Rule 26(b) regardless of whether it is also protected from production by privilege. *Gulfstream Park Racing Ass'n Inc*., 399 F.3d at 400.

B. Abbott Is Not Entitled to Burdensome Discovery of Irrelevant and Privileged Material and Its Motion to Compel Should Be Denied

At the center of Abbott's motion is the assertion that the material which has been withheld from production will "illuminate what the Government knew about prescription drug pricing and the spreads between AWP and actual acquisition costs, as well as reasons for CMS's failure to change its payment methodology in spite of such knowledge." Abbott Mem. at 11. Abbott's purported need for the material at issue rests on a fundamentally flawed premise, which is that the Government's use of an AWP-based payment system that was ultimately susceptible to costly abuse can insulate Abbott from liability for its role in abusing the system. This case, however, is ultimately about Abbott's conduct – more specifically, about Abbott's practice of reporting false prices for its drugs and Abbott's scienter in so doing.

The Court should deny Abbott's motion to compel pursuant to Rule 26 because the material in question is both irrelevant and protected by the deliberative process privilege. Abbott cannot establish that it has any need for the material in light of both the Court's seminal rulings on key legal issues in this case and underlying legal principles. Moreover, Abbott has been provided with, or given access to, documents which detail what the Government knew about prescription drug pricing and the spreads between AWP and actual acquisition costs. Finally, the burden

associated with production of this material outweighs any legitimate benefit that can be achieved by compelling its production.

1. Abbott has Moved to Compel the Production of Deliberative Process Material

Abbott's motion to compel is directed at two very particular categories of material: documents which reflect the deliberations of HHS personnel concerning a) regulations CMS was promulgating and b) legislation under consideration by Congress and other policy initiatives. The case law supporting the deliberative process privilege has been extensively set out in prior briefs by the United States. For the most complete statement of its position, the United States respectfully refers the Court to the United States' Opposition to Defendant Abbott Laboratories, Inc.'s Renewed Motion to Compel Evidence Withheld under the Deliberative Process Privilege (Dkt. 4076).[5]

Abbott asserts that the Government has stated a "blanket refusal" to produce files from CMS's Office of Legislation. This assertion is inexplicable given that the United States has expressly and repeatedly advised Abbott that it would produce correspondence prepared by the Office of Legislation for transmittal to both Congress and outside persons and organizations. The material that is being withheld consists of internal non-public notes and drafts. Similarly, in connection with the Rulemaking Support File, Abbott notes that "CMS received a large number of public comments, including a number of letters from providers" relating to the drug payment

[5] The Rulemaking Support Files are deemed to contain a particularly sensitive category of information by virtue of the authority given to CMS to segregate that type of material from the official rulemaking record. The policy of not releasing these files in response to Freedom of Information Act requests, points up the agency's concern about the sensitive nature of the deliberative material and its interest in restricting its dissemination. *See* Ex. 1, Declaration of L. Parker, ¶ 7. Weighed against that clear expression of concern, there is no minimally sufficient reason to invade the privilege in this case.

levels. Abbott Mem. at 11. Again, as noted above, the Government has been producing the public comment files that are part of the Official Rulemaking Record. The type of material actually withheld by the Government is much narrower than Abbott's brief indicates and there has been no "blanket" refusal.

2. Abbott is Attempting to Obtain Irrelevant Evidence to Re-litigate Issues Already Decided by the Court or First Circuit Precedent

The lack of relevance of the material covered by Abbott's motion is pertinent to two issues. First, under 26(b)(2), a party may be relieved from responding to discovery requests which have no potential to affect the resolution of any legitimate issue in the case. Second and distinct from the first question, were the Court to find some minimal relevance to the material in question, in order to resolve the Government's claim of privilege, the Court would still need to balance the public interest in protection of deliberative material against a party's particularized need for the information in the case. *See, e.g., Committee for Nuclear Responsibility, Inc. v. Seaborg,* 463 F.2d 788, 791 (D.C. Cir. 1971). As will be demonstrated below, Abbott has no legitimate need for the information it is seeking.

On November 2, 2006, after over four and a half years of litigation in this MDL, Judge Saris determined, *as a matter of law,* that the term "AWP" would be construed pursuant to its plain language, and held that the term "means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies." *In Re Average Wholesale Price Litig.,* 460 F. Supp. 2d at 278. The Court thus laid to the rest the major issue that had been in contention in the MDL since its inception. Earlier this year, Judge Saris expressly relied on this holding when entering final judgment against three other defendants in the MDL following a bench trial. *See In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d at 94.

In addition to the impact of these decisions by Judge Saris, Abbott would not be entitled to the information it is seeking in light of clear First Circuit precedent regarding regulatory interpretation. In *United States v. Lachman*, the Court of Appeals held that any interpretive issue relating to a regulation is resolved through reference to the official public record. 387 F.3d 42, 54 (1st Cir. 2004). Any issue about Governmental intent, whether it be in changing a policy or refraining from a policy change, is not resolved by reference to the predecisional deliberations of individuals. As the First Circuit has made clear, "non-public or informal understandings of agency officials concerning the meaning of a regulation are . . . not relevant." *Id.* The "non-public understanding [of individual government officials] of the regulation do not remotely satisfy the requirements of formality and public accessibility" and are not entitled to any deference. *Id.* *See also* Ex. 5, *United States ex rel. Wright v. Agip, et al.*, No. 03-Cv-00264 at 7-9 (E.D. Tex. June 29, 2007) (denying motion to compel deposition of Government personnel regarding their understanding of regulations, and holding that "personal opinions of agency employees that were never communicated to a Defendant are simply irrelevant to either issues of falsity or knowledge").

Properly understood, Abbott's motion relates to the material that has been withheld because its production would expose the deliberations of CMS officials involved in policy-making for the agency. The Government has produced the factual information at issue such as the OIG inspections and audits and associated workpapers. In short, Abbott is not trying to discover what information the Government acquired about drug prices but, rather, is trying to find out what particular CMS officials who participated in the policy deliberations personally thought about factual information collected by the Government. That latter category of information is plainly irrelevant under *Lachman*.

Furthermore, Judge Saris already has addressed the issue of why the Government continued to use AWP as the benchmark for drug payments despite evidence that AWPs reported by some manufacturers for certain drugs were not reflective of market prices. In the Court's June 21 Findings and Conclusions, Judge Saris described the "opaque" nature of pharmaceutical pricing information for physician-administered drugs such as those sold by Abbott (*In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d at 40), and the difficulties in devising non-AWP payment systems (*id.* at 91) despite the Government's emerging recognition of the vulnerability of its payment systems and the need to develop an alternative "pragmatic pricing methodology to handle millions of annual drug transactions." (*id.* at 40-41, 91). Judge Saris also described the Government's efforts to grapple with the problem created by the abusive practices of certain drug manufacturers. *Id.* at 41-46. In particular, she found that the reason it took years for Medicare to "devise an alternative pricing structure [was] because of the complexity of increasing the prices paid for physician services." *Id.* at 91. Judge Saris further noted that "shifting the pricing paradigm from AWP to another approach is like turning the RMS Queen Elizabeth." *Id.*

Abbott's effort to shift the focus of this case to the merits of the Government's drug reimbursement systems is a transparent attempt to deflect attention from its own conduct in creating the problems which the Government then purportedly failed to rectify with sufficient dispatch. The proposition that the Government's awareness that one of its programs may be illegally exploited and that its failure to redesign the program in response thereto somehow restricts its ability to seek redress of fraud is completely without any support in FCA jurisprudence. No court has ever held that the United States is estopped from bringing an FCA action because it refrained from scrapping or even amending a program which may be susceptible to fraud and abuse. *See, e.g., id*. at 94 (finding that, although by the late 1990s "the government

understood that AWP did not represent a true average of wholesale prices,. . . this knowledge does not exonerate defendants"). The premise upon which defendant's discovery and motion to compel are based has no foundation in law or logic. Given the complete lack of relevance, there is no sufficient reason to impose on the Government the substantial burden of further reviewing, logging, or producing this material.

3. The Documents Sought are Irrelevant to Any Issues of Justifiable Reliance With Respect to Abbott's Conduct on the Drugs at Issue

Abbott also argues that the Government must establish that it acted in "justifiable reliance" because it maintained the AWP system of reimbursement during the relevant claims period. However, the issue is whether the Government justifiably relied upon Abbott's price representations on the drugs at issue. The privileged documents Abbott seeks are relevant only if they relate to the issue of whether the United States justifiably relied on Abbott's price representations (1) for the drugs at issue or (2) Abbott drugs generally.

Under the systems that were in place for the payment of drug claims during the period covered by the United States' Complaint,[6] Abbott reported prices for its drugs that it knew would

[6]During the relevant time period, Congress and the Secretary of HHS limited Medicare payments to the lower of the estimated acquisition cost or the national average wholesale price of a drug. 56 Fed. Reg. 59,502, 59,621 (Nov. 25, 1991) (final rule). This regulation governed Part B drug payments until 1997 when it became a statutory requirement. Congress amended the Medicare Act and set Part B drug payments at 95 percent of the average wholesale price. *See* Pub. L. 105-33, 111 Stat. 462-463 (1997). The Secretary amended the Medicare regulations in 1998 to conform with the Balanced Budget Act amendment and, effective January 1, 1999, Medicare paid the lesser of the supplier's actual charge or 95 percent of the national average wholesale price. 63 Fed. Reg. 58,814, 58,905 (Nov. 2, 1998). This payment system remained in place until 2003, when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA). Pub L. 108-173, 117 Stat. 2066 (2003). During the same time frame, a majority of State Medicaid agencies have likewise incorporated published AWPs or Wholesale Acquisition Cost (WAC) into their reimbursement formulae. *See* FAC, ¶¶ 42-44. The Court has held that the term "average wholesale price," as a statutory and regulatory term, *had a plain meaning* during this time frame. *In re Pharm. Indus. Average Wholesale Price*

result in published AWPs and that were inconsistent with the statutory and regulatory scheme. The Government's reliance on those AWPs was pursuant to statute and regulation, not by any agency decision that Abbott's customers deserved to be reimbursed based on whatever AWP Abbott chose to report.

4. The Government's Assertion of Privilege is Sufficient and Effective

In moving to compel production of the material in question, Abbott also asserts that the Government has stated a "catch-all" assertion of the deliberative process privilege and that such a purported "approach is improper under established case law." Abbott Mem. at 13. The United States, however, has not stated a blanket assertion of privilege and the manner in which the Government has asserted the privilege is entirely appropriate.

Rule 26 does not set out an express requirement that a party invoke any privilege via a document-by-document privilege log. Rather, a party simply must "make the claim expressly and shall describe the nature of the documents . . . not produced . . .in a manner that ... will enable other parties to assess the applicability of the privilege or protection." Rule 26(b)(5). The Advisory Committee Notes to the 1993 amendment to Rule 26 explain that a document-level privilege log is not required when preparing such a log may be burdensome based on the volume of material involved:

> The rule does not attempt to define for each case what information must be provided when a party asserts a claim of privilege or work product protection. Details concerning time, place, persons, general subject matter, etc., may be appropriate if only a few items are withheld, but may be unduly burdensome when voluminous documents are claimed to be privileged or protected, particularly if the items can be described by categories.

Litig., 460 F. Supp. 2d at 287

"The basic objective [of the rule] is a sufficient description of the matters withheld to satisfy the needs of the case; rigid insistence on certain logging or indexing procedures may go well beyond that, particularly in larger cases." 8 WRIGHT & MILLER § 2016.1. Accordingly, courts routinely permit litigants to assert privilege claims with respect to categories of material. *See, e.g., SEC v. Thrasher,* 1996 WL 125661 (S.D.N.Y. 1996) (rejecting the need for detailed log where material at issue was voluminous and "a document-by-document listing would [have been] a long and fairly expensive project for counsel to undertake"); *Emerson Elec. Co. v. Ouellette,* 1998 WL 34088465 (D. N.H. 1998) ("the duty to provide a description [of privileged documents] required by Rule 26(b)(5) is flexible and does not arise until there is a good faith challenge to the privilege claim" at which point "a statement asserting that the privilege protects various categories of documents will satisfy Rule 26(b)(5)"(internal citations omitted)).[7]

Finally, there is no uncertainty about the nature of the documents in question. In light of the specificity of Abbott's motion, the nature and content of the files to which it pertains, and the additional information in the attached declarations, the Court is in a position to "assess the applicability of the privilege" – which is the ultimate objective of Rule 26(b).[8]

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[7] Neither of the cases cited by Abbott regarding how a privilege is to be asserted is on point here. Both *Pacific Gas & Electric Co. v. the United States,* 70 Fed. Cl. 128 (2006), *modified on reconsideration by* 71 Fed. Cl. 205 (2006), and *Kaufman v. City of New York*, 1999 WL 239698 (S.D.N.Y. 1999), considered whether assertion of the deliberative process privilege by trial counsel would be effective, and held that the privilege must be asserted by agency personnel. Given that agency personnel have asserted the privilege for the documents at issue here, the cases cited by Abbott are simply inapposite.

[8] The Government is mindful of Local Rule 34.1 which requires that a party state the nature of the privilege claimed with respect to each document withheld based on privilege. The United States believes that the information in the attached declarations satisfies the local rule as read in conjunction with the provisions in Rule 26 and the jurisprudence cited above. However, if the Court is inclined to interpret Local Rule 34.1 to require that the Government individually describe thousands of privileged documents, the United States asks that the Court treat this brief

5. The Magistrate's Order of August 13, 2007 Has Been Stayed

Abbott next argues that the position taken by the Government with respect to the privileged material here "contravenes the August 13, 2007 Order by Magistrate Judge Bowler." Abbott Mem. at 13. Abbott further states that "[a]s it currently stands, the Order requires the Government to produce [certain] documents that it previously withheld under the deliberative process privilege . . . ." *Id.*

On August 30, 2007, however, Judge Saris entered an electronic order granting the Government's motion to stay the August 13 decision by the Magistrate Judge pending a ruling on the cross-objections that were being filed by both Abbott and the United States. Given that the Order of August 13 has been stayed, obviously it cannot provide any legitimate grounds for the current motion to compel.

III. CONCLUSION

For the foregoing reasons, Abbott's motion to compel additional discovery from the United States responsive to RFP Nos. 37 and 38 should be denied.

Respectfully submitted,

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as a request for relief from the logging requirement in the local rule – a form of relief expressly contemplated by the Federal Rules. *See* Comments to 1993 Amendments, Subdivision (b) ("A party can seek relief through a protective order under subdivision (c) if compliance with the requirement for providing [details concerning privileged material] would be an unreasonable burden"). *See also Thrasher,* 1996 WL 125661 at 2 (denying compelled production of privileged material in context of motion for protective order relating to plaintiff's demand for detailed privilege log)

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Dated: November 2, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above MEMORANDUM BY THE UNITED STATES IN RESPONSE TO DEFENDANT ABBOTT LABORATORIES INC.'S MOTION TO COMPEL RESPONSES TO DOCUMENT REQUESTS NOS. 37 AND 38 to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott

Dated: November 2, 2007 Justin Draycott